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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,847	02/13/2002	Harry R. Howard JR.	PC11835A	9027
23913	7590	03/03/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			LIU, HONG	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/075,847

Applicant(s)

HOWARD, HARRY R.

Examiner

Hong Liu

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-30 are pending in this application.

#### ***Election/Restrictions***

Applicants' arguments that Groups I, II and V should be examined together in view of the issued US patent No. 6,410,736 are found persuasive. Therefore, these three groups are combined into one group for examination in this office action.

However, because claim 1 does not have the same scope as that of claim 2, claim 1 should be further restricted from Groups I, II and V.

1. During a telephone conversation with Ms. Donna Grossu on 02/13/04 a provisional election was made with traverse to prosecute the invention of Groups I, II, and V, claims 2-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 22-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

Art Unit: 1624

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 2-21 are drawn to a pharmaceutical composition for the treatment of anxiety or depression comprising a SRI antidepressant and a GABA-A 2/3 agonist. While it is quite well established that antidepressants such as serotonin reuptake inhibitors offer both a good adverse effect profile and efficacy in the treatment of anxiety and depression, the combination of SRI with another pharmaceutical agent such as a GABA agonist is not so well established and thus, warrants further investigation. In a recent review article, Sramek et al. discussed the therapeutic perspectives of various pharmaceutical compounds that are useful in the treatment of generalized anxiety (Drugs, 2002). The authors pointed out the major problem of the newly discovered compounds in treating anxiety, compounds such as serotonin 5-HT<sub>1</sub> receptor agonists, cholecystokinin receptor antagonists, neurokinin receptor antagonists, gabapentin and its analogs, and GABA-A receptor modulators. "These compounds are all in the early stages of investigation, and there are no new therapies expected to be released in the near future (Emphasis added)." The above discussion makes it clear that, at least as of 2002, the year applicants filed this application, much more than routine experimentation would be required to use GABA-A agonist to treat anxiety and depression, let alone the combination of a GABA-A agonist with another pharmaceutical agent. As of 2002, there was only the potential, and that success would require future development, i.e. more than routine experimentation. Additionally, the specification discloses no tests of the in vitro/in vivo efficacy of the combined pharmaceutical composition. Competent evidence

Art Unit: 1624

of art-recognized efficacy for intended uses needs to be provided. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the likelihood of *in vivo* use for all uses being claimed. See *Ex parte Powers*, 220 USPQ 925.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. (WO 99/37303) in view of Howard et al. (WO 01/27068). Dawson discloses a pharmaceutical composition comprising GABA-A 2/3 agonist and a selective serotonin reuptake inhibitor (See the first sentence of the specification). The GABA-A 2/3 agonist in the reference has the formula shown on page 5 (formula I). The reference, however, does not disclose any specific chemical structure of serotonin reuptake inhibitors. Howard et al. teaches a biaryl ether derivative useful as monoamine reuptake inhibitors. The reference compounds have the same formula (page 2 of the reference) as formula II of the instant application. Because the Dawson reference suggests a combination of a GABA-A 2/3 agonist and a selective serotonin reuptake inhibitor in the preparation of a pharmaceutical product to treat anxiety, it would have


Art Unit: 1624

been obvious to one having ordinary skill in the art at the time the invention was made to select compounds of formula (I) in WO 99/37303 as the GABA-A agonist and the compounds of formula (I) in WO 01/27068 as a serotonin uptake inhibitor to make the pharmaceutical composition in the manner taught by Dawson et al. One having ordinary skill in the art would have been motivated to do this so that the combined pharmaceutical composition can be used to treat anxiety and depression (see page 6 of Dawson).

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (571) 272-0669. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisors, Mukund Shah or James Wilson can be reached at (571) 272-0674 or (571) 272-0661, respectively. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 358-1235.



RICHARD L. RAYMOND  
ACTING SPE  
**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**

hl  
February 26, 2004